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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/807,892	06/06/2001	Gavriel Meron	P-1800-US	7467

7590 03/28/2003

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EXAMINER
MANTIS MERCADER, ELENI M

ART UNIT	PAPER NUMBER
3737	10

DATE MAILED: 03/28/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/807,892	MERON ET AL.	
	Examiner	Art Unit	
	Eleni Mantis Mercader	3737	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Peri d for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE _____ MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-53* is/are pending in the application.

4a) Of the above claim(s) *16-22 and 48-53* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15 and 23-47* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *06 June 2001* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *5 &7* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Claims 16-22 and 48-53 withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 9.

Drawings

2. The drawings are objected to because the boxed elements of Figure 6 are not labeled as to the elements they represent. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Claim Objections

3. Claims 2 and 26-33 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The limitations set forth in these claims appear to be apparatus limitations being dependent on method claims. It is unclear as to what method steps are being set forth.

4. Claims 37-47 are objected to because of the following informalities: in claim 37, the use of the term "said data" is inconsistent with "the received data". Examiner suggests replacement of "said data" with --said received data-- to avoid confusion. Appropriate correction is required.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1-8, 23, 31-33 and 36-47 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

7. Claims 1 and 2 recite the limitation "sensing and delivering device" in lines 6 and 1, respectively. There is insufficient antecedent basis for this limitation in the claim.

8. Claims 4 and 5 recite the limitation "the device" in lines 2 and 1, respectively. There is insufficient antecedent basis for this limitation in the claim.

9. Claim 6 is vague and indefinite in that the term "a second pass" in line 5, renders the claim confusing as "a second pass" was set forth in independent claim 1.

10. Claim 23 provides for the use of the method of claim 1 for research, diagnostic or therapeutic purposes, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

11. Claims 31-32 recite the limitation "the operation device" in their respective line 1. There is insufficient antecedent basis for this limitation in the claim.

12. Claim 33 is vague and indefinite in that it is unclear whether "the device" refers to the "first device" or the "second device" of claim 24.

13. Claim 36 recites the limitation "said comparison" in line 2. There is insufficient antecedent basis for this limitation in the claim.

14. Claim 37 recites the limitation "the received data" and "said received data" in lines 4 and 5. There is insufficient antecedent basis for these limitations in the claim.

PLEASE NOTE: The claims are replete with antecedent basis problems and 112 2nd paragraph issues. The Examiner pointed out as many deficiencies as possible. Please revise claims thoroughly to correct for the deficiencies and to avoid further delays in prosecution.

Claim Rejections - 35 USC § 101

15. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

16. Claim 23 provides for the use of the method of claim 1 for research, diagnostic or therapeutic purposes, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim 23 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

16. Claims 37-47 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The use of the term "in-vivo device" implies that a living organism device is used which constitutes non-statutory subject matter.

Claim Rejections - 35 USC § 102

17. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

18. Claims 1-4, 6-9, 12, 23-28, 30-39, 41-43, and 45-47 are rejected under 35 U.S.C. 102(b) as being anticipated by Schentag et al.'607, of record.

Regarding claim 1, Schentag et al.'607, teaches a method of delivering a sensing and utility device to a target location in the gastrointestinal tract comprising the steps of:

generating a map of the gastrointestinal tract employing a sensing and utility device for a first pass through the gastrointestinal tract (col. 3, lines 9-62; referring to the capsule sensing the location in the alimentary canal and having the utility of transmitting signals regarding its location as well as delivering medicaments, wherein the capsule is typically used in a first pass exploratory procedure for mapping the gastrointestinal tract (see in particular col. 3, lines 46-53)); and

delivering said sensing and utility device to a target location identified on said map using said sensing and delivering device in a second pass (col. 3, lines 53-58).

Regarding claims 2, 9, 37, 39, 41, 43, and 45-47, Schentag et al.'607 teach a sensing and utility device for performing a job at a target location in a gastrointestinal tract comprising:

sensing means for generating data in a first and second pass through the gastrointestinal tract (col. 3, lines 4-53; col. 4, lines 21-68 and col. 5, lines 1-18; referring to the radio signal transmitter, which generates data to create a precise map during a first pass (see especially col. 3, lines 28-33 and col. 3, lines 46-53) and subsequently generating data in a second or more passes and comparing that data with the first pass generated map (see col. 3, lines 34-42));

means for signal analysis of the data generated in the first and the second pass (col. 3, lines 18-22 and col. 5, lines 10-18; referring to the comparator/computer means 12 for analysis of the transmitted signal during subsequent passes, including a second pass, with the first pass generated map to determine the current location of the capsule);

means for performing a job in the gastrointestinal tract (col. 5, lines 19-26; referring to medicament releasing assembly causing release of the medicament, from the medicament storage compartment at a location of interest); and

means for controlling the sensing and utility device and the means for performing a job, operable according to said signal analysis (col. 5, lines 3-26; referring to the central processing unit 9 for receiving the transmitted positional signals, analyzing them and triggering treatment at the appropriate location of interest).

Regarding claim 3, Schentag et al.'607 teach inserting the sensing and utility device into the gastrointestinal tract (col. 3, lines 9-10; referring to the ingestion of the capsule in the gastrointestinal or alimentary canal); locating said sensing and utility device (col. 3, lines 18-41 and col. 5, lines 10-18); and displaying the location on a position monitor (col. 5, lines 14-18).

Regarding claims 4, 38, and 42, Schentag et al.'607 teach displaying the location of the device two or three dimensionally (col. 3, lines 28-41 and col. 5, lines 14-18; referring to

mapping of the gastrointestinal tract via first pass and subsequently locating the device in other passes and providing a visual confirmation of its location on a monitor, inherently providing at least a two dimensional image of the gastrointestinal tract by providing the map and the location of the device).

Regarding claim 6, Schentag et al.'607 teach inserting the sensing and utility device into the gastrointestinal tract (col. 3, lines 9-10; referring to the ingestion of the capsule in the gastrointestinal or alimentary canal); receiving data from said sensing and utility device (col. 3, lines 14-18); performing signal analysis of the data generated in the first pass and of the data generated on the second pass (col. 3, lines 28-33 and col. 3, lines 46-53; referring to generating data to create a precise map during a first pass and subsequently generating data in a second or more passes and comparing that data with the first pass generated map (see col. 3, lines 34-42)); and controlling the sensing and utility device according to said signal analysis (col. 5, lines 3-26; referring to the central processing unit 9 for receiving the transmitted positional signals, analyzing them and triggering treatment at the appropriate location of interest).

Regarding claim 7, Schentag et al.'607 teaches that the first pass and the second pass are one or more passes (col. 3, lines 34-42; referring to first mapped route being compared with subsequent plural passes).

Regarding claim 8, Schentag et al.'607 teach that the target location is a location of a pathology (col. 3, lines 53-58; referring to the controlled release of a medicament at a desired site, it is inherent that the desired site is a location of a pathology, otherwise no medicament treatment would be required).

Regarding claim 12, Schentag et al.'607 teach means for performing a job in the gastrointestinal tract that are selected from means for releasing substances into the gastrointestinal tract and means for collecting substances from the gastrointestinal tract (col. 3, lines 53-62 and col. 5, lines 19-26; referring to the means for releasing substances into the gastrointestinal tract).

Regarding claims 24-28 and 30-36, Schentag et al.'607 teach the use of a capsule or the use of multiple capsules in different passes (col. 3, lines 29-42). It is inherent that either a single or an additional capsule is used in different passes having all the limitations as stated above.

Claim Rejections - 35 USC § 103

19. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

20. Claims 10-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schentag et al.'607, of record in view of Lemelson'378, of record.

Regarding claims 10 and 11, Schentag et al.'607 teach all the features of the instant invention including a first and second pass as described above for mapping the gastrointestinal tract, except for a sensing means sensing parameters of the gastrointestinal tract wherein the means for signal analysis analyze the sensed parameters and controlling the capsule based on the analysis. In the same field of endeavors, Lemelson'378 teaches a sensing means to sense parameters of the gastrointestinal tract and wherein the means for signal analysis analyze the sensed parameters (col. 2, lines 1-6; col. 9, lines 29-67; col. 10, lines 1-16; col. 11, lines 1-5; col.

20, lines 53-67 and col. 21, lines 1-7; referring to the swallowing capsule having sensors for detecting physiological parameters of the gastrointestinal tract and transmitting to a shortwave receiver located exterior to the body, having a computer processing and analyzing the transmitted information) and wherein the control of the capsule depends on the analysis of the parameters (col. 21, lines 14-62; referring to treatment based on the analysis).

It would have been obvious to one skilled in the art at the time that the invention was made to have modified Schentag et al.'607 to incorporate the sensing means, transmission of the sensed information, and analysis of such information by a computer, with responsive treatment as taught by Lemelson'378 in order to not only map but to also localize the area of interest in order to treat. Diagnosing with multiple sensors for a variety of possible diseases in the environment of interest and in essence, allowing for real-time analysis of the collected information allowing for responsive treatment based on the analysis, provides an improved diagnosis and treatment tool as taught by Lemelson'378 (motivation for combining all features is described in col. 2, lines 1-46 of Lemelson'378; describing the improved capabilities for diagnosis and treatment provided by sensors and analysis of the sensed information to effectuate treatment).

21. Claims 4-5, 29, 40 and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schentag et al.'607, of record in view of Iddan et al.'531, of record.

Schentag et al.'607 teach all the features of the instant invention including a first and second pass as described above for mapping the gastrointestinal tract, except for displaying of the device two or three-dimensionally and as an overlay to a schematic presentation. In the same field of endeavor, Iddan et al.'531 teach displaying of the device two or three-dimensionally and

as an overlay to a schematic presentation (col. 5, lines 7-16 and col. 6, lines 7-11). It would have been obvious to one skilled in the art at the time that the invention was made to have incorporated and used the system as described in Iddan et al.'531 in the system of Schentag et al.'607, via use of a camera (see Iddan et al.'531, col. 1, lines 55-61, col. 5, lines 7-16, and col. 6, lines 7-11) in order to get a better diagnostic tool of the area of interest via viewing a video of the area of interest as well as its location over a schematic in a two- or three- dimensional display. The user would be able to better verify the area of interest prior to treatment with medicament.

22. Claims 13-15 are rejected under 35 U.S.C. 103(a) as obvious over Iddan et al.'531 in view of Lemelson'378, of record.

Regarding claim 13, Iddan et al.'531 teach a system for delivering a sensing and utility device to a target location in the gastrointestinal tract comprising:

a sensing and utility device consisting of:

a camera system (element 24 of Figure 2 and col. 3, lines 27-34; referring to the CCD camera system);

an optical system for sensing an area of interest onto said camera system (element 26 of Figure 2 and col. 3, lines 33-34; referring to the optical system focusing the images onto the CCD camera);

a transmitter which transmits video output of said camera system (element 28 of Figure 2 and col. 3, lines 34-35; referring to the transmitter which transmits the video signal of the CCD camera);

means for performing a job in the gastrointestinal tract (col. 3, lines 38-40; referring to sensor elements for detecting physiological conditions in the gastrointestinal tract such as pH, temperature and pressure);

a reception system which receives said transmitted video output, said reception system comprising:

an antenna array capable of surrounding the body and comprising a plurality of antennas for receiving said transmitted video output and for producing a plurality of received signals (col. 1, lines 62-66; also see col. 4, lines 27-67; and see Figure 4 antenna array 40);

a demodulator capable of transforming said plurality of received video signals into a single video stream (col. 1, line 67 and col. 2, lines 1-2); and

a data processing system which generates tracking and video data from said single data stream (data processor 14 as described in col. 5, lines 19-67 and col. 6, lines 1-11).

Iddan et al.'531 teach an analyzing unit for signal analysis of the video output. Iddan et al.'531 teach an analysis by which there is recognition of the location of interest in present and past movements of the capsule through the gastrointestinal tract (col. 5, lines 7-16 and col. 5, lines 56-67 and col. 6, lines 1-8).

However, Iddan et al.'531 do not teach an analyzing unit for controlling the sensing and utility device. In the same field of endeavor, Lemelson'378, teaches an analyzing unit for signal analysis and controlling the capsule such as medically treating the area of interest (col. 21, lines 63-67 and col. 22, lines 1-14) as well as use of a video camera (col. 22, lines 53-67).

It would have been obvious to one skilled in the art at the time that the invention was made to have incorporated the controlling aspect of Lemelson'378 to control the capsule of Iddan et al.'531 in order to remotely activate treating the diseased area of interest, such as via medicament release, once the area of interest has been localized or identified via the analyzing unit.

Regarding claims 14 and 15, Iddan et al.'531 teach a sensing and utility device which is swallowable and which is placeable in the gastrointestinal tract (col. 3, lines 13-17).

Conclusion

23. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Alfano et al.'312 teach a remote-controllable, micro-scale device for use in in-vivo medical diagnosis and or treatment.

24. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eleni Mantis Mercader whose telephone number is 703 308-0899. The examiner can normally be reached on Mon. - Fri., 8:00 a.m.-6:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marvin Lateef can be reached on 703 308-3256. The fax phone numbers for the organization where this application or proceeding is assigned are 703 305-3590 for regular communications and 703 308-0758 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308-0858.

Eleni Mantis Mercader
Examiner
Art Unit 3737

EMM
March 24, 2003